Trust for America's Health
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April 21, 2014

Mr. Steven Posnack
Director, Federal Policy Division, Office of Policy and Planning
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: RIN 0991-AB92, Voluntary 2015 Edition Electronic Health Record Certification Criteria: Interoperability Updates and Regulatory Improvements

Dear Director Posnack:

On behalf of Trust for America's Health, thank you for the opportunity to submit comments on the Office of the National Coordinator for Health IT (ONC) proposal on electronic health record (EHR) certification criteria. Trust for America's Health (TFAH) is a non-profit, non-partisan public health advocacy organization dedicated to improving the health of all Americans.

TFAH strongly supports ONC's 2015 Edition proposal to create a field in EHRs to list the unique device identifiers (UDIs) of patients' implanted devices. Creating this field would advance several key public health objectives, including facilitating recalls and identifying high-risk implanted devices with safety problems. We also support the additional functionality being considered for the 2017 Edition, which would greatly enhance the information available to patients and clinicians, without requiring them to utilize an external resource to obtain information on the device.

The UDI system, developed by the Food and Drug Administration (FDA), will provide each medical device with a code corresponding to its make and model in order to unambiguously identify devices used in patient care. By September 2014, the highest-risk implanted devices will be marked with UDIs. Achieving the full benefits of this UDI system, though, requires its adoption in electronic health information—including adverse event reports, materials management systems, device registries, electronic health records (EHR) and claims transactions.

The FDA has listed UDI capture in EHRs as an essential step to achieving the full benefits of this device identification system. Creating a field in EHRs to list the UDIs will dramatically improve care in a number of ways:

- **Better clinical decision support and care coordination:** The inclusion of UDIs in EHRs will allow providers to make more informed decisions on patient care. This information is critical when patients switch providers or see multiple physicians, all of whom may require information on the specific device used in care.
- **Patient engagement:** UDI documentation in EHRs will create an accessible data source for patients to take a more active role in their healthcare by providing a clear source of data on the device implanted in their body.

- **Improved adverse event reports:** Inclusion of UDIs in EHRs will enable patients and providers to submit more precise adverse event reports that identify the make and model – and in some cases lot number – of a potentially malfunctioning device.
- **Enhanced recall resolution:** A list in EHRs of implanted devices will help identify patients implanted with recalled technologies and help them obtain appropriate follow-up care.
- **Analyses on device performance:** Increased data on device utilization can support hospital analyses on product performance in their patients. This information can provide data on outcomes associated with different devices, identify patient subpopulations that respond differently to certain technologies, and provide data on patient selection by physicians for certain products.

To achieve these goals, TFAH supports the 2015 Edition proposal, but also urges ONC to require at least one form of automatic identification and data capture capabilities (AIDC), such as barcoding. Without this, clinicians would have to manually enter the UDI into each EHR, which would likely result in data errors and workflow inefficiencies.

TFAH also supports the 2017 Edition proposal, which would create data fields in EHRs to list more than just the UDI. These fields would state the device manufacturer, model, single use indication, whether it contains latex, and MRI safety status. The proposal would also have these fields automatically populated by an external database. Putting this data directly in the EHR would give patients and doctors critical information without requiring them to go to an external website and manually enter the UDI. The data would also allow hospitals to search through their EHR systems for patients using a certain type of device. We also support the proposed capabilities to ensure that UDIs can be transmitted to reporting systems and registries that collect data on the devices used in care.

We also urge ONC to consider two additional capabilities. We believe EHRs should have the capability to automatically alert clinicians in the event of known device risks with MRI compatibility and latex allergies. Upon ordering an MRI scan or use of a latex-containing product, the provider should receive an automated alert if the patients has an MRI-incompatible device or latex allergy. ONC should also consider how best to provide patients with UDI data, label information and instructions for a device. For example, this information could occur through the incorporation of UDI into patient portals.

UDI capture in EHRs holds the promise of improving clinical care, encouraging patient engagement, and improving patient safety. Thank you for the opportunity to comment on this important proposal. If you need any further information, please contact Becky Salay, TFAH's Director of Government Relations, at 202-223-9870 x15.

Sincerely,

Jeffrey Levi, Ph.D.
Executive Director